NOV 1 6 2004

510(K) SUMMARY

Orchid Diagnostic Ultrasound system

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**

Siemens Medical Solutions USA, Inc., Ultrasound Division
22010 S.E. 51st Street
Issaquah, WA 98029

Contact Person:
Patrick J Lynch
Regulatory Affairs

Phone: (425) 557-1825
FAX: (425) 391-9198

Date Prepared:
September 24, 2004

2. **Proprietary Name:**
SONOLINE Orchid™ Diagnostic Ultrasound System

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

3. **Predicate Device:**
K033196, 10/16/2003, SONOLINE Antares Diagnostic Ultrasound System with Clarify VE
K040060, 01/28/2004, SONOLINE G50&60 S Diagnostic Ultrasound Systems
K040502, 03/09/2004, SONOLINE G20 Diagnostic Ultrasound System

4. **Device Description:**
The Orchid is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in: B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, Harmonic Imaging, or 3D imaging on a CRT display.

The Orchid, has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- IEC 61157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

5. **Intended Uses:**
The Orchid ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. **Technological Comparison to Predicate Device:**
The Orchid is substantially equivalent to the SONOLINE Antares, cleared via K033196, the SONOLINE G50/G60 S, cleared via K040060 and the SONOLINE G20, cleared via K040502. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2004

Siemens Medical Solutions USA, Inc.
% Mr. Mark Job
Responsible Third Party
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K043016
Trade Name: SONOLINE ORCHID Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: October 29, 2004
Received: November 2, 2004

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOLINE ORCHID Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

P4-2 Phased Sector Array
CH5-2 Convex Array

VF10-5 Linear Array
L9-5 Linear Array
EC9-4 Convex Array Endocavity
EV9-4 Convex Array
VF13-5 Linear Array
P7-4 Phased Array
BE9-4 Convex Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **SONOLINE ORCHID Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		BMDC	Note 2,3
Abdominal		N	N	N	N	N	N		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		BMDC	Note 2,3
Small Organ (Note 1)		N	N	N	N	N	N		BMDC	Note 2,3
Neonatal Cephalic		N	N	N	N	N	N		BMDC	Note 3
Adult Cephalic		N	N	N	N	N	N		BMDC	Note 2
Cardiac		N	N	N	N	N	N		BMDC	Note 2,3
Transesophageal										
Transrectal		N	N	N		N	N		BMDC	Note 2,3
Transvaginal		N	N	N		N	N		BMDC	Note 2,3
Transurethral										
Intravascular										
Peripheral vessel		N	N	N	N	N	N		BMDC	Note 2,3
Laparoscopic										
Musculo-skeletal Conventional		N	N	N	N	N	N		BMDC	Note 2,3
Musculo-skeletal Superficial		N	N	N	N	N	N		BMDC	Note 2,3
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Eglman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2** Phased Sector Array Transducer for use with:
SONOLINE ORCHID Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N	N	N	N			Note 2,3
Abdominal		N	N	N	N	N	N		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N			Note 2,3
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic		N	N	N	N	N	N		BMDC	Note 2,3
Cardiac		N	N	N	N	N	N		BMDC	Note 2,3
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CH5-2** Convex Array Transducer for use with:
SONOLINE ORCHID Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		BMDC	Note 2,3
Abdominal		N	N	N		N	N		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		BMDC	Note 2,3
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N	N	N		N	N		BMDC	Note 2,3
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF10-5** Linear Array Transducer for use with:
SONOLINE ORCHID Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		BMDC	Note 2,3
Small Organ (Note 1)		N	N	N		N	N		BMDC	Note 2,3
Neonatal Cephalic		N	N	N		N	N		BMDC	Note 2,3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N	N	N		N	N		BMDC	Note 2,3
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		BMDC	Note 2,3
Musculo-skeletal Superficial		N	N	N		N	N		BMDC	Note 2,3
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **L9-5** Linear Array Transducer for use with:
SONOLINE Orchid Diagnostic Ultrasound Systems

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		BMDC	Note 2,3
Small Organ (Note 1)		N	N	N		N	N		BMDC	Note 2,3
Neonatal Cephalic		N	N	N		N	N		BMDC	Note 2,3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N	N	N		N	N		BMDC	Note 2,3
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		BMDC	Note 2,3
Musculo-skeletal Superficial		N	N	N		N	N		BMDC	Note 2,3
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lagrow
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EC9-4** Convex Array Endocavity Transducer for use with: SONOLINE ORCHID Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		BMDC	Note 2,3
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		BMDC	Note 2,3
Transvaginal		N	N	N		N	N		BMDC	Note 2,3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Clayman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EV9-4** Convex Array Transducer for use with:
SONOLINE ORCHID Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		BMDC	Note 2,3
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N		BMDC	Note 2,3
Transvaginal		N	N	N		N	N		BMDC	Note 2,3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5** Linear Array Transducer for use with:
SONOLINE ORCHID Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N		BMDC	Note 2,3
Small Organ (Note 1)		N	N	N		N	N		BMDC	Note 2,3
Neonatal Cephalic		N	N	N		N	N		BMDC	Note 2,3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N	N	N		N	N		BMDC	Note 2,3
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N	N		BMDC	Note 2,3
Musculo-skeletal Superficial		N	N	N		N	N		BMDC	Note 2,3
Other (specify)										

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Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
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Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P7-4** Phase Array Transducer for use with:
SONOLINE ORCHID Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		BMDC	Note 2,3
Abdominal		N	N	N	N	N	N		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		BMDC	Note 2,3
Small Organ (Note 1)										
Neonatal Cephalic		N	N	N	N	N	N		BMDC	Note 2,3
Adult Cephalic										
Cardiac		N	N	N	N	N	N		BMDC	Note 2,3
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculc-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043016

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **BE9-4** Convex Array Transducer for use with:
SONOLINE ORCHID Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		BMDC	Note 2,3
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N	N	N	N		BMDC	Note 2,3
Transvaginal		N	N	N	N	N	N		BMDC	Note 2,3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

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Note 2 Ensemble tissue harmonic imaging
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Note 4 B&W SieScape panoramic imaging
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Note 7 Contrast agent imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043016